UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,

Plaintiff,

v.

Case No. 2:21-cv-10312

BLUEWILLOW BIOLOGICS, INC.; ROBIN ROE 1 through 10, gender neutral fictitious names, and; ABC CORPORATION 1 through 10 (fictitious names).

Hon. Stephen J. Murphy, III
Mag. R. Steven Whalen

Defendants.

DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW BIOLOGICS, INC.'S OPPOSITION TO TRUTEK'S MOTION FOR LEAVE TO AMEND

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STATEMENT OF ISSUE PRESENTED

1. Whether this Court should deny Plaintiff/Counter-Defendant's Motion for Leave to Amend the Complaint to accuse new products after the close of discovery.

Plaintiff/Counter-Defendant's answer: **No**.

Defendant/Counter-Plaintiff's answer: **Yes**.

TABLE OF AUTHORITIES

Cases

Statutes

I. INTRODUCTION

Defendant BlueWillow Biologics, Inc. ("BlueWillow") reiterates, this is a classic nuisance patent lawsuit in which Plaintiff Trutek Corp. ("Trutek") is seeking to extort a settlement based on the cost of defending against a patent infringement suit. Trutek has continuously delayed progress in this case and it is clear that Trutek has no interest in prosecuting this case on reasonable terms.

Trutek has missed ***every*** discovery deadline thus far. In an attempt to further delay, after the already extended close of discovery, Trutek now wishes to start this case all over and accuse a laundry list of additional products that are merely in development, are not approved by the FDA, and have never been sold ("**Developmental Vaccine Candidates**")—despite an Order from this Court that expressly stated discovery would not be extended absent agreement between the parties. Courts will deny motions to amend when there is undue delay, bad faith or dilatory motive, undue prejudice, or where amendment would be futile. While only one is required, all are present here.

First, Trutek's Motion should be denied for undue delay. Discovery has closed and there is a Court Order declaring that, to avoid prejudice, discovery would not be extended without BlueWillow's consent. Trutek cannot succeed on the merits without discovery—particularly on products that have not been commercially sold, are still under development and subject to eventual FDA

approval. By necessary implication, Trutek's Motion should be denied. Trutek also provides no meaningful explanation for why it decided to accuse BlueWillow's Developmental Vaccine Candidates now—except for a bare assertion of "new information." Notably, Trutek raised the issue of the vaccines during early discussions, in an October 2021 Letter, (**Ex. E**), and again during the Scheduling Conference in November 2021, yet the asserted "new information" consists of publicly available[1] information that was available to Trutek well before it filed its original Complaint (*e.g.*, patents published prior to this lawsuit—i.e., by BlueWillow's predecessor—and articles and press releases from as far back as 2000). (Dkt. 28-1, PgID 295–312.) Trutek's belief that there are other infringing products is based solely on the fact that BlueWillow's predecessor obtained various patents years ago, information that was known and/or available to Trutek before this case was filed. There is no excuse for Trutek's delay here.

Second, Trutek's Motion should also be denied for dilatory motive. BlueWillow provided Trutek with citations to relevant case law holding that discovery cannot be used to go fishing for additional products to accuse. In response, Trutek filed a bare bones motion to amend without even addressing this

[1] Patents and published applications are searchable on the United States Patent Office's website. *See Search for Patents*¸ USPTO (last visited May 25, 2022), https://www.uspto.gov/patents/search. A permanent link for a search conducted on May 25, 2022 can be found at https://perma.cc/2ABA-MJ2J.

case law. Trutek now seeks to have the Court open a backdoor for discovery about products Trutek has never examined, but speculates might infringe its patent. More egregiously, BlueWillow's activities directed to its Developmental Vaccine Candidates are protected under the safe harbor of 35 U.S.C. § 271(e)(1) and are not properly the subject of a patent infringement suit at this stage (if ever). Trutek's attempt to add these products to the case, only a few weeks prior to the Court-ordered Mediation, suggests that Trutek does not intend to engage in good faith reasonable efforts to resolve the matter.

Third, Trutek's Motion should be denied for futility as the proposed amended complaint would not survive a motion to dismiss. For one, Trutek's bare and conclusory infringement allegations are insufficient to satisfy *Twombly/Iqbal*. For another, under the safe harbor described above, BlueWillow is broadly shielded from an infringement claim for conduct related to testing of products for purposes of regulatory approval. While Trutek has been on notice of BlueWillow's position on this issue for over a year, it (again) chose not to address this argument—other than a conclusory (uncited) assertion that it is BlueWillow's burden to prove the safe harbor applies. Nevertheless, the safe harbor does apply, and dismissal of Trutek's allegations would be appropriate under relevant case law, rendering Trutek's proposed amendment futile.

Finally, BlueWillow would be unduly prejudiced if Trutek's motion is granted. Despite being aware of the issues raised in its proposed Amended Complaint, Trutek delayed bringing this motion until just weeks before the mediation scheduled for June 14, 2022. Moreover, allowing Trutek to proceed with its claims of infringement against the vaccine products, particularly where Trutek's allegations on their face demonstrate the applicability of the safe harbor, would undermine the very purpose of the safe harbor, subjecting BlueWillow "to the same burdensome litigation that Congress sought to eliminate." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 112-13 (D. Mass. 1998).

Trutek's Motion should be denied.

II. BACKGROUND

BlueWillow is a clinical-stage biopharmaceutical company focused on developing intranasal vaccines for challenging respiratory infections, sexually transmitted diseases, and food allergies. (Dkt. 9, Counterclaim, ¶ 6.) BlueWillow also developed and sold NanoBio® Protect, an over-the-counter nasal antiseptic that uses BlueWillow's proprietary technology to deliver benzalkonium chloride (BZK), a common skin antiseptic that has been used in over-the-counter products for more than 75 years. (*Id.* ¶ 7.) NanoBio® Protect is now discontinued and is no longer sold in the U.S.

On **February 10, 2021**, Trutek filed suit alleging one count of patent infringement of United States Patent No. 8,163,802 ("the '802 Patent") against BlueWillow with respect to a single product, NanoBio® Protect. (Dkt. 9, Counterclaim ¶ 6; Dkt. 1, Complaint). The '802 Patent is attached as Exhibit 6 to the Complaint. (Dkt. 1-6.) Trutek's Complaint alleges that BlueWillow's NanoBio® Protect directly infringes "at least claims 1, 2, and 7 of the ['802] Patent because the [NanoBio® Protect] products possess an electrostatic charge when applied to a person's nasal passages, and they use benzalkonium chloride as a biocide." (Dkt. 9, Counterclaim, ¶ 9; Dkt. 1, Complaint, ¶ 30.)

On **May 19, 2021**, BlueWillow filed its responsive pleading, including its Counterclaims. (Dkt. 9.) Since that time, Trutek has not prosecuted its case.

On **November 03, 2021**, the Court entered a scheduling order stating that fact discovery shall be completed by April 1, 2022. Yet, Trutek failed to issue a single discovery request before this deadline.

On **February 18, 2022**, BlueWillow issued its First Set of Document Requests and Interrogatories. On **March 2, 2022,** BlueWillow served its Second Set of Requests for Production.

On **March 18, 2022**, Trutek filed a motion to extend the scheduling order by 45 days. (Dkt. 24.) On **March 23, 2022**, the Court granted the motion, extending fact discovery to May 16, 2022, and witness disclosures to May 11, 2022. The

Court "warn[ed] Plaintiff that there will be no further extensions to these deadlines unless the parties agree to extend a deadline." (Dkt. 26, PgID 269.)

Notably, while Trutek's motion did not request, and the resulting Order did not grant, an extension on Trutek's time to respond to discovery requests, BlueWillow (in a show of good faith) operated as it had. Nevertheless, Trutek failed to timely respond to BlueWillow's First Set of Requests for Production and Interrogatories even assuming a 45-day extension. Trutek only responded (incompletely) after being notified that its objections had been waived. (**Ex. D**, May 11, 2022 Email from L. Peterson to K. Altman and S. Kremen.)

Trutek subsequently failed to timely respond to BlueWillow's Second Set of Requests for Production—which was due on May 16, 2022[2] (the last day for the close of discovery). As of the date of this Opposition, BlueWillow has not received such responses.

Trutek also failed to meet the deadline for witness list disclosures.[3] (*See* Dkt. 29 (two days late).)

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[2] Assuming the generous interpretation that Trutek received a 45-day extension as to discovery requests.

[3] BlueWillow timely served its witness list disclosure by the deadline in the original Scheduling Order (March 30, 2022) and served an updated witness list disclosure by the new deadline as well (May 11, 2022). (**Ex. F**, Service Emails.) BlueWillow also timely served its responses to Trutek's requests for admission and

On **May 11, 2022**, Trutek issued its first set of document requests to BlueWillow, only 5 days before the close of the discovery deadline (as amended). Although there is only one accused product in this case—NanoBio® Protect—Trutek's requests are extensive (numbering 53 total requests), and are almost entirely directed to the non-accused Developmental Vaccine Candidates. A true and correct copy of Trutek's First Set of Requests for Production is attached hereto as **Exhibit A**. For example, Request No. 3 asks for "[a] list of physical properties of ***every*** BlueWillow product . . . ." (emphasis added). Request No. 4 asks for a "sample of BlueWillow's vaccine created to produce an immune response against *bacillus anthracis*." Request No. 5. Asks for "[a] list of all ingredients in the formulation of BlueWillow's vaccine created to produce an immune response against *bacillus anthracis*."

On the **same day**, Trutek filed the instant Motion seeking leave to amend the Complaint. (Dkt. 28.)

III. STANDARD OF REVIEW

Federal Rule of Civil Procedure 15(a)(2) provides that a party may amend its pleading with the court's leave and that "the court should freely give leave when justice so requires." Denial of a motion to amend is appropriate, however,

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interrogatories according to the 30-day period in the Federal Rules for Civil Procedure. (**Ex. F**, Service Emails.)

where there is "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of the amendment, etc." *Morse v. McWhorter*, 290 F.3d 795, 800 (6th Cir. 2002).

IV. ARGUMENT

A. Trutek's Motion Should be Denied for Undue Delay

Recognizing the risk of granting Trutek's prior request to extend discovery, the Court stated, "[t]o minimize any prejudice that may result from extending discovery, the Court will warn Plaintiff that there will be no further extensions to these deadlines unless the parties agree to extend a deadline." (Dkt. 26, PgID 269.) This should end the discussion as the operative fact discovery deadline of May 16, 2022 has elapsed, and the law of the case is that the deadline cannot be extended without BlueWillow's consent.

Nevertheless, the case law is clear that Trutek's Motion is untimely for additional reasons. In *Bridgeport Music, Inc. v. Dimension Films*, 410 F.3d 792, 806–807 (6th Cir. 2005), the Sixth Circuit affirmed a district court's denial of leave to amend with only a few weeks of discovery remaining. *See also R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427, 440–441 (6th Cir.2005) (affirming denial of leave where discovery was complete). In this case, fact discovery is closed.

Trutek has offered no meaningful explanation for why it seeks to accuse BlueWillow's Developmental Vaccine Candidates now, instead of when it filed its original complaint or even shortly after the Scheduling Conference when the issue was first raised with the Court. *See Scott v. Hemlock Semiconductor Corp.*, No. 06-14903-BC, 2007 WL 2649360, at *3 (E.D. Mich. Sept. 10, 2007) (denying motion to amend where no explanation was given for why a claim was not brought in the previously filed complaint). This suit was filed in February 2021, and Trutek's 15-month delay is inexcusable. *See Springs v. Mayer Brown LLP*, No. 11–CV–13518, 2013 WL 656494, at *1 (E.D. Mich. Feb. 22, 2013) (describing 14-month delay as "inexcusable").

Trutek asserts "information is available now that could not have been and in fact was not available to TRUTEK before the filing of this motion." This argument is facially spurious. ***First***, Trutek did not serve its First Set of Requests for Production until the same day it filed the motion for leave. *See Odish v. Peregrine Semiconductor, Inc.*, No. 2:13-CV-14026, 2014 WL 12659591, at *1 (E.D. Mich. Nov. 17, 2014) (rejecting vague assertion that the complaint seeks to "address newly discovered evidence").

Second, attachments to Exhibit A to Trutek's Motion identifies press releases going back as far as September 22, 2015, and a list of articles going back as far as 2000. (Dkt. 28-1, PgID 295–312.) Exhibit B is a declaration stating that

the ***predecessor*** of BlueWillow obtained patents that tend to indicate "BlueWillow vaccines ***probably*** utilize the technology disclosed in the Nanobio patents." (Dkt. 28-2, PgID 313–322, ¶¶ 10–18 (emphasis added).) All of this information was publicly available and obtained by Trutek's counsel through public sources. Yet Trutek offers no explanation for why it did not and could not have obtained this information earlier. Moreover, while Trutek did serve requests for admission and interrogatories, which BlueWillow timely responded to, none of the information provided by BlueWillow in its discovery responses is cited by Trutek in support of its motion to amend as new information that it could not have obtained earlier.

Third, there can be no legitimate dispute that Trutek was aware of its flawed infringement theory concerning BlueWillow's developmental vaccine candidates at least six months before filing its motion to amend, if not longer. Exhibit A to Trutek's Motion (Kremen Declaration) refers to certain patents assigned to the Regents of the University of Michigan that are asserted to relate to BlueWillow. (Dkt. 28-1, ¶¶ 10–11.) Exhibit B to Trutek's Motion (Lemmo Declaration) references a list of Nanobio patents that Dr. Lemmo purportedly reviewed in rendering his "opinion." (Dkt. 28-2, ¶ 4.) Notably, Mr. Kremen does not specifically identify when he conducted his "searches" (Dkt. 28-1, ¶¶ 10–11) and Dr. Lemmo does not state when he was retained to review the patents or render his "opinion" (Dkt. 28-2, ¶ 3.) In fact, Dr. Lemmo conducted his review of this

information no later than October 23, 2021, more than six months ago. (**Ex. E**, October 25, 2021 Email from S. Kremen to L. Peterson attaching Dr. Lemmo's October 23, 2021 Letter.) More specifically, in his October 23, 2021 Letter, Dr. Lemmo identifies the Nanobio patents referenced in Exhibit B to Trutek's Motion (Lemmo Declaration) as well as the Regents of the University of Michigan patents referenced in Exhibit A to Trutek's Motion (Kremen Declaration).[4]

In summary, Trutek's stated basis for believing that BlueWillow's Developmental Vaccine Candidates are "probably" infringing is the existence of publically available information, including patents obtained by BlueWillow's predecessor, well before this case was filed. As detailed above, Trutek was aware of and possessed this information months before filing its motion to amend – at least as early as October 2021. Trutek has no legitimate justification for its delay.

B. Trutek's Motion Should be Denied for Bad Faith/Dilatory Motive

As BlueWillow has explained to Trutek, courts will not permit a Defendant to use discovery to obtain information on products that are not at issue in this suit—which constitutes an improper fishing expedition. *See, e.g., Samsung SDI Co., Ltd. v.*

[4] Moreover, any suggestion that Trutek was not aware of BlueWillow's objections to discovery of the developmental vaccine candidates until BlueWillow served its responses to Trutek's requests for admission on May 2, 2022 (Dkt. 28-1, ¶ 20) is incorrect as well. Counsel for BlueWillow notified Trutek of its position on the developmental vaccine candidates as early as April 2021 and again leading up to and during the November 2021 scheduling conference. Indeed, Trutek sent a letter from Dr. Lemmo addressing the vaccines in October 2021. (*See* **Ex. E**.)

Matsushita Elec. Indus. Co., Ltd., No. CV 05-8493-AG(SHx), 2007 WL 4302701, at *2 (C.D. Cal. June 27, 2007); *Biax Corp. v. Nvidia Corp.*, 271 F.R.D. 200, 205 (D. Colo. Sept. 21, 2010); *Moore U.S.A., Inc. v. Standard Register Co.*¸ No. CIV.A.97–CV–2054A, 1998 WL 34016835, at *6 (E.D. Va. Mar. 20, 1998); *Oplus Tech., Ltd. v. Sears Holdings Corp.*¸ No. 2:12-cv-05707-MRP-Ex, 2013 WL 12130253, at *1 (C.D. Cal. Oct. 2, 2013); *see also Micro Motion, Inc. v. Kane Steel Co., Inc.*, 894 F.2d 1318, 1327 (Fed. Cir. 1990). Trutek's bad faith attempt to engage in an unbridled fishing expedition is clear as, among other things, Trutek simultaneously served discovery requests that inquire into *all* of BlueWillow's products and vaccines.[5] (*See generally* **Ex. A**.) Moreover, Trutek only filed this instant Motion after receiving BlueWillow's formal objections to discovery requests directed to the non-accused Developmental Vaccine Products (*see* **Ex. B**, May 9, 2022 Objections to Interrogatory No. 4), despite being on notice of BlueWillow's objections for a significantly longer period of time, (Dkt. 28-1, ¶ 19). Notably, courts will not grant leave to amend when it is for the improper purpose of

[5] For example, Request No. 3 asks for "[a] list of physical properties of ***every*** BlueWillow product . . . ." (emphasis added). Request No. 4 asks for a "sample of BlueWillow's vaccine created to produce an immune response against *bacillus anthracis*." Request No. 5. Asks for "[a] list of all ingredients in the formulation of BlueWillow's vaccine created to produce an immune response against *bacillus antracis*."

conducting discovery or a fishing expedition. *See, e.g.*, *Kozlowski*, No. 2:13–cv–00291–JAM–DAD, 2014 WL 1329889, at *4 (C.D. Cal. Mar. 28, 2014) ("The Court found (and continues to find) that the FAC was filed against Defendant Southwell in bad faith for the improper purpose of conducting discovery against Defendant Southwell.").

Indeed, patent holders are required to conduct a reasonable pre-filing investigation before alleging infringement pursuant to Federal Rule of Civil Procedure 11. *See Thermolife Int'l LLC v. GNC Corp.*, 922 F.3d 1347, 1356 (Fed. Cir. 2019) ("Plaintiffs did not conduct an adequate pre-suit investigation into infringement by Defendants. That determination would suffice to support the exceptional-case determination."). That is clearly not the case here.

C. Trutek's Motion Should be Denied for Futility

Trutek's proposed amended complaint is futile as: (1) the allegations are improperly conclusory and speculative; and (2) the safe harbor of 35 U.S.C. § 271(e)(1) precludes liability. *See Doe v. Mich. State Uni.*, 989 F.3d 418, 424 (6th Cir. 2021) (an amendment is futile when it cannot withstand a motion to dismiss).

First, the allegations are improperly conclusory and speculative. Generally, courts construe a complaint in the light most favorable to the plaintiff and accept all well-pleaded factual allegations as true. *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009). However, the court "does not apply this presumption of truth to conclusory

or legal assertions." *Binno v. American Bar Association*, 826 F.3d 338, 345–46 (6th Cir. 2016). A complaint for patent infringement is not well pled when it merely includes a "list[] [of] various product lines of Defendant[], without any facts upon which Plaintiff grounds its claim." *Prestige Pet Prods., Inc. v. Pinyqn Huaxing Leather & Plastic Co. Ltd.*, 767 F.Supp.2d 806, 810 (E.D. Mich. 2011). "Stripped of its legal conclusions unsupported by factual allegations . . . Plaintiff's minor premise reduce to []: Defendants manufacture or sell products with characteristics that appear similar to products made using Plaintiff's patented" technology. *Id.* at 811. Absent more, "there exists in the instant case an 'obvious alternative explanation' that provides no grounds for relief . . . ." *Id.*

That is the case here. Plaintiff merely asserts that BlueWillow and/or the Regents of the University of Michigan have patents related to vaccine technology and then systematically repeats conclusory allegations that, "on information and belief," these vaccines infringe each limitation of various patent claims. (*See* Dkt. 28-4, ¶¶ 25–44.) Stripped of such conclusory legal conclusions, Plaintiff's proposed amended complaint insufficiently alleges a mere possibility of infringement. *See Iqbal*, 556 U.S. at 679.

Second, 35 U.S.C. § 271(e)(1), the safe harbor statute, precludes a claim of infringement under these circumstances. Section 271(e)(1) provides that "[i]t shall not be an act of infringement to . . . use . . . or import into the United States a

patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the . . . use . . . of drugs." As long as the safe harbor applies, it "does not look to the underlying purposes or attendant consequences of the activity." *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997).

The Supreme Court has stated that the exemption is broad and "extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the [FDA]." *Merck KGaA v. Integra Lifesciences, I. Ltd.*, 545 U.S. 193, 202 (2005). The Supreme Court also held that the safe harbor's protection is so expansive as to cover drugs for which no application or information was ultimately submitted to the FDA. *Id.* at 206. Thus, the protection applies when a drug maker merely "has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA." *Id.* This provision clearly applies to Trutek's allegation that "BLUEWILLOW is currently developing vaccines, and it has been doing so for a

number of years" and "some or all of the . . . vaccines infringe at least claims 1 and 2 of Trutek's '802 Patent." (Dkt. 28-4, ¶¶ 36 & 40.)[6]

Without citing any authority, Trutek suggests that it does not need to plead facts sufficient to establish that the Section 271(e)(1) safe harbor does not apply because it is an affirmative defense. This is incorrect. Indeed, Courts routinely dismiss complaints for patent infringement on the basis of the Section 271(e)(1) safe harbor even if it is an affirmative defense. "The safe harbor provision in 35 U.S.C. § 271(e)(1) may properly be considered at the motion to dismiss stage, even if it is viewed as an affirmative defense." *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, 993 F. Supp. 2d 569, (D. Md. 2014) (dismissing complaint based on safe harbor provision and stating "the Court may consider affirmative defenses on a motion to dismiss where they are clear from the face of the complaint"); *see also Med. Diagnostic Labs, LLC v. Protagonist Therapeutics, Inc.*, 298 F.Supp.3d 1241, 1249 (N.D. Cal. 2018) (dismissing complaint for failing to plead facts sufficient to plausibly defeat safe harbor provision).

Here, application of the Section 271(e)(1) safe harbor is clear from the face of the complaint. Paragraphs 41 and 42 of Trutek's proposed Amended Complaint allege that the vaccines are "currently undergoing phased trials to determine safety

[6] The redline of Trutek's amended complaint (Dkt. 28-3) appears to be different from the clean version of the amended complaint (Dkt. 28-4).

and efficacy." (Dkt. 28-4, ¶¶ 41-42.) This is precisely the activity that 35 U.S.C. § 271(e)(1) exempts from infringement. 35 U.S.C. § 271(e)(1) ("It shall not be an act of infringement to . . . use . . . or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the . . . use . . . of drugs."). In other words, Trutek's proposed Amended Complaint clearly implicates the Section 271(e)(1) safe harbor as it asserts that "BlueWillow is currently developing vaccines," the vaccines are "currently undergoing phased trials to determine safety and efficacy" and "the BlueWillow vaccines . . . infringe on the '802 Patent" (Dkt. 28-4, ¶¶ 36, 41–42, 49). Conducting clinical trials to demonstrate safety and efficacy are a key requirement toward obtaining FDA approval, and as such, fall squarely within the safe harbor. *See Shionogi*, 993 F. Supp. 2d at 574 ("Activities carried out to satisfy FDA requirements fall within the safe harbor.").

The Amended Complaint further alleges that BlueWillow "has not yet realized revenue from sales of its vaccine products," demonstrating that BlueWillow's activities are not commercial and thus, do not fall outside of the safe harbor. (Dkt. 28-4, ¶ 44.) Likewise, the bare allegation that BlueWillow "is collaborating with third parties in its vaccine development effort" (Dkt. 28-4, ¶ 43) is conclusory, does not identify the third parties or specific collaboration efforts, and thus lacks any factual basis. Nor does Trutek argue, or cite any authority, that

third party collaborations fall outside the safe harbor. Thus, even if this allegation was well pled and accepted as true, it does not state a claim that is plausible on its face demonstrating that BlueWillow's activities fall outside of the safe harbor and are subject to a claim for infringement. *Shionogi*, 993 F. Supp. 2d at 574.

Similarly, in *Carl Zeiss v. Topcon Medical System, Inc.*, the plaintiff did not assert any facts from which one could conclude that defendant's alleged infringing activity was not protected by the § 271(e)(1) safe harbor. No. 19-cv-04162-SBA, ECF No. 285, pp. 13–16 (N.D. Cal. July 21, 2021) (attached as **Exhibit C**). There, the court rejected the plaintiff's arguments that testing was for commercialization efforts and not for FDA approval. The court reasoned, application of the safe harbor "does not turn on whether [a defendant] eventually intends to commercialize [a product]. Rather, as long as the activity is reasonably related to obtaining FDA approval, the court does not look to the underlying purposes or attendant consequences of the activity." *Id.* The court thus dismissed the patent infringement claim without leave to amend. *See also Shionogi*, 993 F. Supp. 2d at 569; *Teva Pharma. USA, Inc. v. Sandoz Inc.*, No. 10112, 2013 WL 3732867 (S.D.N.Y. July 16, 2013) (same); *Classen Immunotherapies, Inc. v. Biogen Idec*, 381 F. Supp. 2d 452 (D. Md. 2005) (same).

Trutek's arguments that the Court should hear its claims of patent infringement directed to BlueWillow's developmental vaccine candidates now,

instead of upon FDA approval and commercial marketing when the safe harbor no longer applies (Dkt. 28 at 2-3), are equally unavailing. While Trutek has not pled a claim for declaratory relief,[7] that is what Trutek is requesting by asking this Court to determine if the vaccine products will infringe in the future, if they are approved by the FDA and commercially marketed. Even if this issue were properly in front of this Court in the proposed Amended Complaint, Trutek's argument has been soundly rejected by other courts because it runs directly counter to the purpose of the Section 271(e)(1) safe harbor.

As explained in *Amgen*, "[n]ot only is FDA approval uncertain, but the process or the product itself may be altered during the interval in ways that are material to an infringement analysis." *Amgen*, 3 F. Supp. 2d at 112 (explaining that any "declaration issued by this Court now may be rendered moot by such alterations"). In declining to exercise jurisdiction to hear claims of future infringement where the safe harbor applied, the *Amgen* court further explained:

> More important, subjecting the Defendants to an infringement litigation at present may run afoul of the Congressional policy underlying the section 271(e)(1) exemption. The purpose of the clinical trials exemption is to expedite the arrival of generic drugs on the market upon the expiration of a patent.
>
> * * *

[7] Trutek's claims for patent infringement are brought only under 35 U.S.C. § 271(e)(1). Trutek has not pled that the Court also has jurisdiction to issue a declaration concerning BlueWillow's purported future infringement.

> Declaratory judgment actions have the potential to discourage and hamper the very efforts that Congress sought to stimulate, by subjecting potential competitors to the same burdensome litigation that Congress sought to eliminate. Although it is true that Amgen seeks only a declaration of its rights, which would not preclude continuing exempt activities, the use of the declaratory action could easily become a tool of harassment and intimidation for use in discouraging early efforts at competition. Because the Defendants in this case will violate the law only if they step outside the protective safe harbor that Congress has created, this Court is hesitant to invade that harbor under the auspices of declaratory relief.

Id. at 112–13.

As admitted by Trutek in the proposed amended complaint, BlueWillow's vaccines are still in development and undergoing pre-clinical and clinical trials. BlueWillow has not submitted an application for FDA approval, and any such approval is uncertain at this stage and likely years away. Likewise, the vaccines may be altered over the course of that process, or may never be approved. For all of the foregoing reasons, granting Trutek's motion to amend would be futile as the complaint would not survive a motion to dismiss. Likewise, entertaining jurisdiction to hear Trutek's claims of infringement directed to the vaccines at this stage is premature, and to do so would run afoul of the safe harbor and would likely discourage the very same activity that the safe harbor is intended to protect.

D. BlueWillow Will Be Unduly Prejudiced if Trutek's Motion to Amend is Granted

Contrary to Trutek's assertion (Dkt. 28 at 2–3), BlueWillow will be unduly prejudiced if Trutek's motion to amend is granted. BlueWillow will likewise be

prejudiced if Trutek is allowed the opportunity to extend discovery for the purpose of obtaining additional fact discovery on the safe harbor.

From the outset, it has been clear that the amount in controversy does not justify the expense or use of judicial resources to litigate Trutek's claims of infringement directed to NanoBio Protect®. BlueWillow had long suggested that the matter was appropriate for an early settlement conference or mediation. Despite being aware of BlueWillow's position on the safe harbor for well over a year, and being in possession of the information it now relies on to assert infringement of the vaccine products for at least 6 months, Trutek delayed in filing its motion until just weeks before the Court-ordered mediation scheduled for June 14, 2022.

This issue was raised at the Scheduling Conference, where Trutek indicated that it needed discovery on whether the safe harbor applies. Despite this representation, Trutek did not seek any discovery during the original fact discovery period. Trutek obtained an extension, and did serve interrogatories and requests for admission on BlueWillow, many of which were directed to application of the safe harbor and to which BlueWillow responded. Trutek should not be given yet another opportunity to take additional discovery through this Motion, where it already had the opportunity to and did in fact take such discovery. There is nothing further that Trutek could seek to discover now that it has not already asked for, or should have asked for earlier, given that this issue has been known to Trutek for

well over a year. For the reasons explained herein, Trutek's delay is inexcusable, particularly in view of the upcoming mediation, and this Court has already recognized the potential prejudice of further extensions.

Likewise, Trutek's new claims directed to the vaccines are without merit and subject to dismissal. As explained by the *Amgen* court, the prejudice to BlueWillow is apparent. Allowing Trutek to proceed with its claims of infringement directed to the vaccine products would "discourage and hamper the very efforts that Congress sought to stimulate, by subjecting [BlueWillow] to the same burdensome litigation that Congress sought to eliminate" and could be viewed as "a tool of harassment and intimidation for use in discouraging early efforts at competition." *Amgen*, 3 F. Supp. 2d at 112–13.

V. CONCLUSION

For the reasons stated herein, BlueWillow requests that the Court deny Trutek's Motion in its entirety, without leave to amend or renew.

Dated: May 25, 2021

Respectfully submitted,

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CERTIFICATE OF ELECTRONIC SERVICE

I hereby certify that on May 25, 2021, I electronically filed the foregoing document and accompanying exhibits with the Clerk of the Court for the Eastern District of Michigan using the ECF System, which will send electronic notice to all participants.

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